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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,395	01/31/2002	Paul Young	PZ004G22YP1D1	9708
22195	7590	02/26/2004	EXAMINER	
HUMAN GENOME SCIENCES INC 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			MARTINELL, JAMES	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 02/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,395

Applicant(s)

YOUNG ET AL.

Examiner

James Martinell

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/31/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12, 23-32, 38-2, and 48-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "the secreted portion" (claims 7, 23, 38, and 39) is vague and indefinite because the secreted portion of ATCC Deposit No. 97923 is not defined in the application.
- (b) Claims reciting a percentage sequence identity to the molecule encoded in the ATCC Deposit (claims 23, 24, 28, and 29) are vague, indefinite, and incomplete because the sequence of the insert in ATCC Deposit No. 97923 is not clear and is not definitely disclosed. Thus, it is not possible for one of skill in the art to know what the metes and bounds of the claims are.
- (c) Claims reciting fragments of the molecule encoded in the ATCC Deposit (claims 38, 39, 48, and 49) are vague, indefinite, and incomplete because the sequence of the insert in ATCC Deposit No. 97923 is not clear and are is definitely disclosed. Thus, it is not possible for one of skill in the art to know what the metes and bounds of the claims are.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 1-52 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. There is no specific, substantial, and credible utility disclosed for SEQ ID NO: 142 or claimed fragments or variants thereof. The lists on pages 32-33 are no more than vague hoped for uses that those of skill in the art might hunt for in order to use the claimed polypeptides. They are not a disclosure of specific, substantial, and credible utilities for an invention in its current (*i.e.* as of the filing date) form. See *Brenner v. Manson*, Supreme Court of the U.S., 148 USPQ 689 (1966).

Claims 1-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the rejection under 35 USC § 101 hereinabove is incorporated here.

Claims 13-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those polypeptides for which a fixed sequence is disclosed, does not reasonably provide enablement for all of the polypeptides embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant application does not give one of skill in the art enough guidance to make and use polypeptides that are not of a disclosed fixed sequence that has activity. The Court of Appeals for the Federal Circuit found that claims reciting polypeptides with multiple amino acid substitutions were broader than the enabling disclosure. See *Amgen v. Chugai* (18 USPQ2d 1016, Fed. Cir. 1991)). *Amgen* applies here because the instant application gives no guidance to those of skill in the art as to how to make and use sequence variants that fall within the scope of the claims. It is noted that the court alluded to at least some evidence of this sort in *Amgen* (*e.g.*, see page 1027, column 2, first full paragraph). The instant application gives even less guidance than in *Amgen*.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


James Martinell, Ph.D.
Primary Examiner
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